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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,049	09/27/2005	M. Vittoria Chiesa	26963U	4645

34375 7590 03/06/2007

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER	
GRAZIER, NYEEMAH	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,049	CHIESA ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-11, 14* is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. ACTION SUMMARY

Claims 1-11, 13 and 14 are currently pending. Claim 12 has been canceled.

II. PRIORITY

This application is a 371 of PCT/EP04/50428, filed on April 2, 2004. Applicant's claim to foreign priority pursuant to 35 U.S.C. 119 (a-d) to European Patent Office (EPO) 03007780.4, filed on April 4, 2003 is acknowledged.

III. INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on December 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

IV. REJECTION

CLAIM REJECTIONS - 35 USC § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for treating gastrointestinal diseases, the specification does not reasonably provide enablement for the prevention of gastrointestinal diseases.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these

claims. The relevant factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been set forth in *In re* Wands. See *In re* Wands, 8 USPQ.2d 1400 (1988). The factors are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The factors that are relevant to this rejection are factors (3) predictability or lack thereof in the art, (5) the presence of working examples, and (6) the breadth of the claims. For clarity, the analysis of 112, first paragraph will be separated into each factor.

The Predictability or Lack Thereof in the Art

A greater amount of evidentiary support is needed to satisfy the requirement of 35 U.S.C 112, first paragraph because of the high level of unpredictability associated with "prevention" of diseases. The pharmaceutical art is unpredictable and requires the embodiments to be individually assessed for physiological activity. Thus, the more unpredictable the art, more information in support of the invention is required to satisfy the statute. See In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

First there are a wide range of gastrointestinal disorders and depending on the disorder and more importantly the etiology. The applicant has provided some insight regarding inhibition of gastric proton/potassium - ATPase by using imidazol[1,2-a]pyridines having antiulcer activity. The biological data suggested that the inhibitory activity using in vitro models is predictive of their in vivo gastric antisecretory activity, but not predictive of inhibitory activity when the agent is administered orally.

The Amount of Direction or Guidance Present

The specification sets forth the advantages of using the compounds and compositions for commercial utility. The terms "gastrointestinal disorders" include gastric ulcers, peptic ulcer, including peptic ulcer bleeding, duodenal ulcer gastritis, hyperacidic or medicament-related functional dyspepsia. See, Specification, p. 52-53. The Specification provides some data using rat models. Table A on page 56 of the Specification shows in vivo data of inhibition of acid secretion. The data provided is vague. Select compounds at 1mpk have greater than 50% inhibiton. This does not suggest that the invention has 99-100% inhibition and therefore does not provide information indicative of the full scope of the invention. Namely, prevention of all gastrointestinal disorders.

The Presence or Absence of Working Examples

The specification fails to bridge the gap between the compounds inhibitory effects sufficient to prove that the invention could be used to prevent any and all gastrointestinal disorders and the effects of the compound when administered to a patient. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See *In re* Riat (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re* Barr (CCPA 1971) 444 F 2d 349, 151 USPQ 724. T No examples have been set forth describing the prevention of said disease.

The Breadth of the Claims

The claim is broad and seeks protection under the Patent Act to use the invention of Formula (I) to treat and prevent gastrointestinal disorders.

V. OBJECTION

The specification is objected to for the following reasons: Pages 25, 36, and 52 contain spaces or partially blank pages. Correction is required.

VI. CLOSEST ART

The instant invention is drawn to cyclic benzimidazoles of formula (1) and the method of using said compounds for treating gastrointestinal disorders. The instant invention appears to be free

of the art of record. The closest prior art reference of record is Altana Pharma AG (WO 03014123 A1). The instant invention is not anticipated nor rendered obvious by the in art of record because the prior art of record teaches tricyclic imidazopyridines while the instant invention is drawn to imidazo[4,5-h]quinoline and pyrano-benzimidazole derivatives.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

Nyeemah Grazier, Esq.
Patent Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-8781

KAMALA SAIED, PH.D.
PRIMARY EXAMINER

for **Joseph K. McKane**
Supervisory Primary Examiner, Art Unit 1626
UNITED STATES PATENT AND TRADEMARK OFFICE
400 Dulany Street
Alexandria, VA 22314-5774
Tel. No.: (571) 272-0699